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EXAMINER

CUMBERLEDGE, JERRY L

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3733

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/811,636

Applicant(s)

MCDEVITT ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 29-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 29-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/29/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29-31, 33-35, 40-43, 45, 46 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Choung (US Pat. 6,332,778).

Choung discloses an apparatus for attaching tissue to bone comprising: an expandable body (Fig. 2, refs. 50 and 10)(column 4, lines 60-63) configured to expand into bone, said expandable body defining a bore (Fig. 2, ref. 19); an expander pin (Fig. 2, refs. 16 and 60) comprising a shaft (Fig. 2, ref. 30) sized to be received in the bore of said expandable body (Fig. 2) and expand said expandable body laterally when said expander pin is driven into said expandable body (Figs. 2 and 3); and tissue attachment means (Fig. 2, refs. 40 and 20) associated with said shaft; whereby when said expander pin is driven into said expandable body, said expandable body is attached to the bone and said tissue attachment means secures the tissue to said apparatus. The expander pin includes fastener stabilization apparatus (Fig. 2, threads

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on ref. 30) for stabilizing said expander pin relative to said expandable body. The fastener stabilization apparatus comprises threads (Fig. 2, threads on ref. 30). The tissue attachment means comprises at least one laterally-extending projection for tacking tissue (Fig. 2, top edge of ref. 20; Fig. 2, bottom, rounded edge of ref. 40). The at least one laterally-extending projection has a substantially linear outer edge (Fig. 2, top edge of ref. 20). The at least one laterally-extending projection has a substantially arc-like outer edge (Fig. 2, bottom, rounded edge of ref. 40). The expandable body is provided with a tapered distal end (Fig. 2, tapered portion near ref. 11). The expandable body comprises a distal tip member (Fig. 2, ref. 50) and a proximal main member (Fig. 2, ref. 10), said distal tip member being separable from said proximal main member (column 5, lines 30-31). The distal tip member and said proximal main member are threadedly interengageable with one another (Fig. 2, near ref. 11). The distal tip member and said proximal main member are frictionally interengageable with one another (Fig. 2, near ref. 11). The expandable body distal tip member is tapered (Fig. 2, tapered portion near ref. 50). The expandable body includes bone securement apparatus (Fig. 2, ref. 12) for securing said expandable body relative to bone. The bone securement apparatus comprises threads (Fig. 2, ref. 12). The apparatus further comprises a pusher member (column 5, lines 34-36) configured to drive said expander pin into said expandable body. The pusher member slides along said shaft when driving said expander pin into said expandable body. The at least one laterally-extending projection has a substantially convex configuration (Fig. 2, bottom, rounded edge of ref. 40). The at least one laterally-extending projection has a substantially

planar configuration (Fig. 2, top edge of ref. 20). The at least one laterally-extending projection has a substantially concave configuration (Fig. 2, concave portion to the right of ref. numeral 42).

Choung discloses an apparatus for attaching tissue to bone comprising: an expandable body (Fig. 2, refs. 10 and 50)(column 4, lines 60-63) defining a bore (Fig. 2, ref. 19) and configured to expand into bone, said expandable body comprising a distal tip member (Fig. 2, ref. 50) and a proximal main member (Fig. 2, ref. 10), said distal tip member having a threaded recess (Fig. 2, opening near ref. 54) in a proximal surface (Fig. 2, ref. 54) thereof and said proximal main member having a distally extending threaded projection (Fig. 2, ref. 11) threadedly interengageable with the distal tip member recess (Fig. 2); an expander pin (Fig. 2, refs. 16 and 60) comprising a shaft (Fig. 2, ref. 30) sized to be received in the bore of said expandable body (Fig. 2) and expand said expandable body laterally when said expander pin is driven into said expandable body (Figs. 2 and 3); and tissue attachment means associated with said shaft (Fig. 2, refs. 40 and 20); whereby when said expander pin is driven into said expandable body, said expandable body is attached to the bone and said tissue attachment means secures the tissue to said apparatus. The expander pin includes fastener stabilization apparatus (Fig. 2, threads on ref. 30) for stabilizing said expander pin relative to said expandable body. The fastener stabilization apparatus comprises threads (Fig. 2, threads on ref. 30). The tissue attachment means comprises at least one laterally-extending projection (Fig. 2, top edge of ref. 20; Fig. 2, bottom, rounded edge of ref. 40) for tacking tissue. The at least one laterally-extending projection has a

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substantially linear outer edge (Fig. 2, top edge of ref. 20). The at least one laterally-extending projection has a substantially arc-like outer edge (Fig. 2, rounded edge of ref. 40). The expandable body distal tip is tapered (Fig. 2, tapered portion near ref. 11). The expandable body includes a bone securement apparatus (Fig. 2, ref. 12) for securing said expandable body relative to bone. The bone securement apparatus comprises threads (Fig. 2, ref. 12). The apparatus further comprises a pusher member (column 5, lines 34-36) configured to drive said expander pin into said expandable body. The pusher member slides along said shaft when driving said expander pin into said expandable body.

Choung discloses an apparatus for attaching tissue to bone comprising: an expandable body (Fig. 2, refs. 50 and 10)(column 4, lines 60-63) configured to expand into bone; said expandable body comprising a distal tip member (Fig. 2, ref. 50) and a proximal main member (Fig. 2, ref. 10), said distal tip member having a threaded recess (Fig. 2, opening near ref. 54) in a proximal surface (Fig. 2, ref. 54) thereof and said proximal main member having a distally extending threaded projection (Fig. 2, ref. 11) threadedly interengageable with the distal tip member recess (Fig. 2), and an opening (Fig. 2, ref. 19) extending from a distal end of said expandable body to a proximal end of said expandable body)(see Fig. 1, opening further continues through ref. 50, which appears to be mislabeled as ref. 20, at very bottom of figure), said opening being sized to receive said shaft of said installation tool; an expander pin (Fig. 2, refs. 16 and 60) comprising a shaft (Fig. 2, ref. 30) sized to be received in said opening in said expandable body (Fig. 2) and expand said expandable body radially

when said expander pin is driven distally into said expandable body (Figs. 2 and 3), and tissue attachment means (Fig. 2, refs. 40 and 20) associated with said shaft of said expander pin, said expander pin defining a bore sized to receive said shaft of said installation tool; and tissue attachment means associated with at least one of said expandable body and said expander pin; whereby when said expander pin is driven into said expandable body, said expandable body will be attached to bone and said tissue attachment means will secure tissue to said apparatus.

Choung discloses an apparatus for attaching tissue to bone comprising: an expandable body (Fig. 2, refs. 50 and 10)(column 4, lines 60-63) configured to expand into bone and comprising a distal tip member (Fig. 2, ref. 50) and a proximal main member (Fig. 2, ref. 10), said distal tip member having a threaded recess (Fig. 2, opening near ref. 54) in a proximal surface (Fig. 2, ref. 54) thereof and said proximal main member having a distally extending threaded projection (Fig. 2, ref. 11) threadedly interengageable with the distal tip member recess (Fig. 2), and said expandable body defining an opening (Fig. 2, ref. 19); an expander pin (Fig. 2, refs. 16 and 60) comprising a shaft (Fig. 2, ref. 30) sized to be received in said opening in said expandable body (Fig. 2) and expand said expandable body radially when said expander pin is driven into said expandable body (Figs. 2 and 3); and tissue attachment apparatus (Fig. 2, refs. 40 and 20) associated with at least one of said expandable body and said expander pin; whereby when said shaft is connected to said expandable body, and said expander pin is driven into said expandable body, said

shaft can provide a counterforce to said expandable body so as to counteract the driving force applied to said expander pin.

With regard to statements of intended use and other functional statements (e.g. ...configured to expand into bone..., ...sized to be received in the bore of said expandable body..., ...frictionally interengageable with one another..., ...the pusher member slides along said shaft when driving said expander pin into said expandable body..., ...whereby when said expander pin is driven into said expandable body, said expandable body is attached to the bone and said tissue attachment means secures the tissue to said apparatus..., etc.), they do not impose any structural limitations on the claims distinguishable over the device of Choung, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-7, 12-13, 15, 44 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choung (US Pat. 6,332,778) in view of Osada (US Pat. 6,162,236).

Choung discloses the claimed invention except for said distal tip member being of harder material than said proximal main member.

Osada discloses a distal tip member (Fig. 11, ref. 78)(column 11, lines 7-9) being made of a harder material (column 11, lines 10-16) than a proximal main member (Fig. 11, ref. 24)(column 13, lines 25-30). The distal tip member is made of this material so that it can pierce tissue (column 10, lines 8-16), and the proximal main member is made of this softer material so that it can have elasticity, airtightness, and durability (column 13, lines 25-27) so that it can expand when a device having an outside diameter greater than an inside diameter of the front end is inserted into it (column 2, lines 43-47).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the distal tip member of Choung with a harder material than the proximal main member of Choung as taught by Osada, in order to allow the distal tip portion to pierce tissue (column 10, lines 8-16) and the proximal main member to expand in response to a device having an outside diameter greater than an inside diameter of the end being inserted into it (column 2, lines 43-47).

Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choung (US Pat. 6,332,778) in view of Osada (US Pat. 6,162,236) further in view of Nicholson et al. (US Pat. 5,725,529).

Regarding claim 4, Choung in view of Osada disclose the claimed invention except for the fastener stabilization apparatus comprising ribs.

Nicholson discloses a fastener stabilization apparatus (Fig. 5, ref. 34) comprising ribs (Fig. 5, ref. 38), which are useful for engaging an expandable member's inner channel (column 8, lines 56-59).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the fastener stabilization apparatus of Choung in view of Osada with the ribs of Nicholson, in order to allow the fastener stabilization device of Choung in view of Osada to engage the inner channel of the expandable body of Choung in view of Osada (column 8, lines 56-59).

Regarding claim 14, Choung in view of Osada disclose the claimed invention except for the bone securement apparatus comprising ribs.

Nicholson discloses the bone securement apparatus (Fig. 3, ref. 10) comprising ribs (Fig. 3, ref. 16), in order to allow the bone securement apparatus to engage irregularities in the bone opening wall as the expandable member deforms and conforms to the bone opening wall during and after expansion (column 6, lines 20-24).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the bone securement apparatus of Choung in view of Osada with the ribs of Nicholson, in order to enable the bone securement

apparatus Choung in view of Osada to engage irregularities in the bone opening wall as the expandable member deforms and conforms to the bone opening wall during and after expansion (column 6, lines 20-24).

Claims 8, 9, 10, 16-22 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choung (US Pat. 6,332,778) in view of Osada (US Pat. 6,162,236) further in view of Stone et al. (US Pat. 5,370,662).

Regarding claims 8, 9 and 10, Choung in view of Osada disclose the claimed invention except for the tissue attachment means comprising a bore formed in said expander pin and a suture extending through said expander pin bore; the tissue attachment means is configured so that said suture is slidable relative to said expander pin when said expander pin is received in said expandable body; the tissue attachment means further comprises a second bore formed in said expander pin and a second suture extending through said second expander pin bore; the tissue attachment means further comprises at least one longitudinally-extending projection projecting distally out of at least one laterally-extending projection (Fig 8A, ref. 91).

Stone et al. disclose tissue attachment means comprising a pin (Fig. 8B, entirety) with a bore (Fig. 8B, ref. 50a) formed therein, and a suture extending through the bore (column 4, lines 41-44), the tissue attachment means is configured so that the suture is slidable relative to the pin, since the sutures are merely threaded through the bores (e.g., see Fig. 1); the tissue attachment means further comprises a second bore (Fig. 8B, ref. 50a) formed in the expander pin and a second suture extending through the

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second expander pin bore (column 8, lines 56-58); the tissue attachment means further comprises at least one longitudinally-extending projection (Fig. 8A, ref. 54) projecting distally out of at least one laterally-extending projection (Fig 8A, ref. 91). This bore and suture arrangement is useful for accepting a driving tool (column 6, lines 52-54).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the tissue attachment means of Choung in view of Osada with the bores and sutures of Stone et al., in order to provide a suture arrangement that is useful for accepting a driving tool (column 6, lines 52-54).

Regarding claims 16-22, 27, 28 and 63, Choung in view of Osada disclose the claimed invention except for the apparatus further comprising an installation tool, and wherein said installation tool comprises a shaft sized to be slidably received in said bore of said expandable body and a bore of said expander pin; the shaft is releasably attachable to said expandable body. The shaft and said expandable body are threadably interengageable with one another; the shaft is provided with a tapered distal end; the shaft extends distally beyond said expandable body when said shaft is slidably received in said bore of said expandable body.

Stone et al. disclose an apparatus further comprising an installation tool (Fig. 8F, refs. 20 and 60), and wherein said installation tool comprises a shaft (Fig. 8F) sized to be slidably received in a bore (Fig. 8E, bore through middle of ref. 10) of a fastener body (Fig. 8E, ref. 10); the shaft is releasably attachable to said body; the shaft and the body are threadably interengageable with one another, since the shaft is threaded into the body (e.g. how a thread is threaded through the body of a needle); the shaft is

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provided with a tapered distal end (Fig. 8F, ref. 72, end to the right); the shaft extends distally beyond said body when said shaft is slidably received in said bore of said expandable body (Fig. 8E). This device is used to drive the body and to guide the leading tip of the body into a pilot hole in the target bore (column 6, lines 52-60).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have included the insertion tool of Stone et al. with the expandable body of Choung in view of Osada, in order to drive the expandable body of Choung in view of Osada and to guide the leading tip of the body of Choung in view of Osada into a pilot hole in the target bone (column 6, lines 52-60).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Choung (US Pat. 6,332,778) in view of Osada (US Pat. 6,162,236) further in view of Bonutti (US Pat. 5,948,002).

Choung in view of Osada discloses the claimed invention except for the expander pin having indicia for indicating depth.

Bonutti discloses a pin (Fig. 11, ref. 92c) inserted into a bore which includes depth indicia (column 39, lines 36-38), to indicate the depth which the suture anchor has been placed into tissue (column 39, lines 26-36).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the expander pin of Choung in view of Osada with the depth indicia on a pin which is inserted into a bore of Bonutti, in order for

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the expander pin to indicate to a user how far the suture anchor has been placed into a bone (column 39, lines 26-36).

Claims 23-26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Choung (US Pat. 6,332,778) in view of Osada (US Pat. 6,162,236) further in view of Moll et al. (US Pat. 5,078,718).

Choung in view of Osada discloses the claimed invention except for the apparatus further comprising a cannulated driver assembly adapted to drive said expander pin into said expandable body. The cannulated driver assembly slides along a shaft connected to said expandable body. The cannulated driver assembly includes a trigger for inducing the driving of said expander pin. The cannulated driver assembly comprises a slap hammer.

Moll et al. discloses a cannulated driver assembly (a slap-hammer) (column 7, lines 13-15), a connector for connecting the driver assembly to a sleeve (column 7, lines 13-15) and a trigger (Fig. 3G, knob at top of device), the driver assembly being used to apply impact tension to a sleeve (column 7, lines 15-17).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the apparatus of Choung in view of Osada to further include a slap-hammer connected to a sleeve as taught by Moll et al., in order to apply impact tension to the expandable body of Choung (column 7, lines 15-17).

Claims 32 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chuong (US Pat. 6,332,778) in view of Nicholson et al. (US Pat. 5,725,529).

Regarding claim 32, Chuong discloses the claimed invention except for the fastener stabilization apparatus comprising ribs.

Nicholson discloses a fastener stabilization apparatus (Fig. 5, ref. 34) comprising ribs (Fig. 5, ref. 38), which are useful for engaging an expandable member's inner channel (column 8, lines 56-59).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the fastener stabilization apparatus of Chuong with the ribs of Nicholson, in order to allow the fastener stabilization device of Chuong to engage the inner channel of the expandable body of Chuong (column 8, lines 56-59).

Regarding claim 47, Chuong discloses the claimed invention except for the bone securement apparatus comprising ribs.

Nicholson discloses the bone securement apparatus (Fig. 3, ref. 10) comprising ribs (Fig. 3, ref. 16), in order to allow the bone securement apparatus to engage irregularities in the bone opening wall as the expandable member deforms and conforms to the bone opening wall during and after expansion (column 6, lines 20-24).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the bone securement apparatus of Chuong with the ribs of Nicholson, in order to allow the bone securement apparatus to engage

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irregularities in the bone opening wall as the expandable member deforms and conforms to the bone opening wall during and after expansion (column 6, lines 20-24).

Claims 36-38 and 49-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choung (US Pat. 6,332,778) in view of Stone et al. (US Pat. 5,370,662).

Regarding claims 36-38, Choung discloses the claimed invention except for the tissue attachment means comprising a bore formed in said expander pin and a suture extending through said expander pin bore; the tissue attachment means is configured so that said suture is slidable relative to said expander pin when said expander pin is received in said expandable body; the tissue attachment means further comprises a second bore formed in said expander pin and a second suture extending through said second expander pin bore; the tissue attachment means further comprises at least one longitudinally-extending projection projecting distally out of at least one laterally-extending projection (Fig 8A, ref. 91).

Stone et al. disclose tissue attachment means comprising a pin (Fig. 8B, entirety) with a bore (Fig. 8B, ref. 50a) formed therein, and a suture extending through the bore (column 4, lines 41-44), the tissue attachment means is configured so that the suture is slidable relative to the pin, since the sutures are merely threaded through the bores (e.g., see Fig. 1); the tissue attachment means further comprises a second bore (Fig. 8B, ref. 50a) formed in the expander pin and a second suture extending through the second expander pin bore (column 8, lines 56-58); the tissue attachment means further

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comprises at least one longitudinally-extending projection (Fig. 8A, ref. 54) projecting distally out of at least one laterally-extending projection (Fig 8A, ref. 91). This bore and suture arrangement is useful for accepting a driving tool (column 6, lines 52-54).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the tissue attachment means of Choung with the bores and sutures of Stone et al., in order to provide a suture arrangement that is useful for accepting a driving tool (column 6, lines 52-54).

Regarding claims 49-55, Choung discloses the claimed invention except for the apparatus further comprising an installation tool, and wherein said installation tool comprises a shaft sized to be slidably received in said bore of said expandable body and a bore of said expander pin; the shaft is releasably attachable to said expandable body. The shaft and said expandable body are threadably interengageable with one another; the shaft is provided with a tapered distal end; the shaft extends distally beyond said expandable body when said shaft is slidably received in said bore of said expandable body.

Stone et al. disclose an apparatus further comprising an installation tool (Fig. 8F, refs. 20 and 60), and wherein said installation tool comprises a shaft (Fig. 8F) sized to be slidably received in a bore (Fig. 8E, bore through middle of ref. 10) of a fastener body (Fig. 8E, ref. 10); the shaft is releasably attachable to said body; the shaft and the body are threadably interengageable with one another, since the shaft is threaded into the body (e.g. how a thread is threaded through the body of a needle); the shaft is provided with a tapered distal end (Fig. 8F, ref. 72, end to the right); the shaft extends

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distally beyond said body when said shaft is slidingly received in said bore of said expandable body (Fig. 8E). This device is used to drive the body and to guide the leading tip of the body into a pilot hole in the target bore (column 6, lines 52-60).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have included the insertion tool of Stone et al. with the expandable body of Choung, in order to drive the expandable body of Choung and to guide the leading tip of the body of Choung into a pilot hole in the target bone (column 6, lines 52-60).

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Choung (US Pat. 6,332,778) in view of Bonutti (US Pat. 5,948,002).

Choung discloses the claimed invention except for the expander pin having indicia for indicating depth.

Bonutti discloses a pin (Fig. 11, ref. 92c) inserted into a bore which includes depth indicia (column 39, lines 36-38), to indicate the depth which the suture anchor has been placed into tissue (column 39, lines 26-36).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the expander pin of Choung with the depth indicia on a pin which is inserted into a bore of Bonutti, in order for the expander pin to indicate to a user how far the suture anchor has been placed into a bone (column 39, lines 26-36).

Claims 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choung (US Pat. 6,332,778) in view of Moll et al. (US Pat. 5,078,718).

Choung discloses the claimed invention except for the apparatus further comprising a cannulated driver assembly adapted to drive said expander pin into said expandable body. The cannulated driver assembly slides along a shaft connected to said expandable body. The cannulated driver assembly includes a trigger for inducing the driving of said expander pin. The cannulated driver assembly comprises a slap hammer.

Moll et al. discloses a cannulated driver assembly (column 7, lines 13-15), a connector for connecting the driver assembly to a sleeve (column 7, lines 13-15) and a trigger (Fig. 3G, knob at top of device), the driver assembly being used to apply impact tension to a sleeve (column 7, lines 15-17).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the apparatus of Choung to further include a slap-hammer connected to a sleeve as taught by Moll et al., in order to apply impact tension to the expandable body of Choung (column 7, lines 15-17).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 27 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 47 of prior U.S. Patent No. 6,733,506. This is a double patenting rejection.

Claim 28 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 48 of prior U.S. Patent No. 6,733,506. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 47 of U.S. Patent No. 6,733,506.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the application claims and the patent claims

lies in the fact that the patent claims include more elements and are thus more specific. Thus the invention of the patent claims are in effect a "species" of the "generic" invention of the application claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the patent claims, they are not patentably distinct from the patent claims.

Response to Arguments

Applicant's arguments filed 05/30/2007 have been fully considered but they are not persuasive.

With regard to Applicant's argument that the term tissue attachment means must be interpreted to cover the corresponding structure, material or acts described in the specification and equivalents thereof, the Examiner respectfully disagrees. According to MPEP 2181, a claim limitation will be presumed to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3 prong-analysis:

- (A) the claim limitations must use the "means for" or "step for;"
- (B) the "means for" or "step for" must be modified by functional language; and
- (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

In this case, the claimed element does not meet (A) and (B). As the claim currently stands, the Examiner is not considering 112, sixth paragraph to be invoked.

Furthermore, for the sake of argument, even if 112, sixth paragraph is considered to be invoked, the device of Choung does include lateral projections (Fig. 2, refs. 40 and 20) (Fig. 2, top edge of ref. 20; Fig. 2, bottom, rounded edge of ref. 40).

With regard to Applicant's argument that it would not have been obvious to combine any of the references cited with Choung since the Choung reference is directed towards a dental implant and the other devices are not even remotely applicable to a dental implant, the Examiner respectfully disagrees. The devices used by the Examiner in the rejections under 35 U.S.C. 103(a) are all analogous art, since the devices all come from the surgical art. Furthermore, some of the devices are used as suture anchors, which is highly analogous to the function being performed by the Choung references. Rather than holding a suture in place, however, the device of Choung holds a dental implant in place. Naturally, one looking to modify a device that is implanted into the body in order to hold another implant or device in place would look towards other surgical devices that perform similar functions (e.g. suture anchors) in order to improve the device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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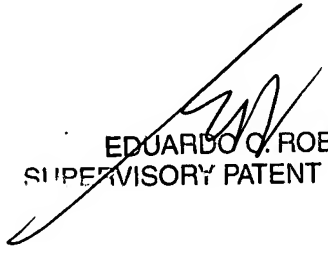
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



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